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EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	23

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/495,448	Applicant(s) LAU, LESTER F.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-25* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 9-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-8,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *22* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

The Amendment filed May 27, 2003 (Paper No. 21) in response to the Office Action of March 25, 2003 is acknowledged and has been entered.

Claim 25 was added.

Claims 1-4, and 6-25 are pending.

Claims 1-3, 9-23 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 4, 6-8, and 24-25 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 4, 6-8, and 24 remain rejected and Claim 25 is rejected as vague and indefinite for reciting the term "Cyr61" in association with binding characteristics as the sole means of identifying the claimed molecule for the reasons of record in Paper No. 21, page 3.

Applicants argue (Paper No. 21, page 5) that the Examiner has applied an improper standard of definiteness. Applicants argue that it is a fundamental principle that applicants are their own lexicographers wherein Applicants can define in the claims what they regard as their invention in whatever terms they choose so long as the terms make clear the boundaries of the

subject matter for which protection is sought. Applicants (page 6) submit that the specification provides numerous teachings for of ordinary skill in the art to reasonably ascertain the meaning of "Cyr61". Applicants point to page 22, lines 19-26 wherein the specification teaches that Cyr61 is a secreted 41kDA polypeptide exhibiting 39 cysteine residues. Applicants further point out that the specification discloses the amino acid sequence of representative Cyr61 polypeptides in Figure 1. Additionally, applicants argue that the proper consideration is not whether other laboratories may use the same designation to define completely distinct molecules as noted in the rejection, but the proper inquiry is whether the teachings of the prior art are contrary to the claim language thereby making an otherwise definite claim take on an unreasonable degree of uncertainty. Here, applicants argue that the prior art polypeptide in question (Cyr61) has been referenced in the prior art such that one of ordinary skill in the art would be able to ascertain the scope of the claims with reasonable certainty.

These arguments have been considered but are not found persuasive because it cannot be ascertained what is considered a "Cyr61" polypeptide thus rendering the claimed subject matter indefinite. True, the specification points out that Cyr61 is a secreted 41kDA polypeptide exhibiting 39 cysteine residues. Yet, the specification also points out (page 22) that Cyr61 can encompass human forms (SEQ ID NO:4) and murine forms (SEQ ID NO:2). However, a sequence search of SEQ ID NO:2 revealed 100% homology to a polypeptide with a different laboratory designation (see sequence comparison attached at the end of this action). In EP495674-A2, Brunner *et al.* teach (Figure 4) an isolated polypeptide called "βIG-M1" which is exactly the same polypeptide referred to as murine Cyr61 in the present application. Thus, one of ordinary skill in the art may confuse Cyr61 with βIG-M1. Further, the specification teaches

(page 48, line 28+) that the polypeptides of the invention also extend to fragments, analogs, and derivatives of the full-length polypeptides. Since the specification does not define that which is encompassed by Cyr61 fragments, Cyr61 analogs, or Cyr61 derivatives, one of ordinary skill in the art could not ascertain the scope of the claims with reasonably clarity because the specification fails to disclose with reasonably certainty that all such modified proteins are in fact Cyr61 polypeptides and are capable of functioning as to that which is being claimed. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6-8, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth a method for screening a modulator of cell migration comprising forming a gel matrix comprising SEQ ID NO:2 (murine Cyr61) or SEQ ID NO:4 (human Cyr61) and therefore the written description is not commensurate in scope with the claims which read on forming a gel matrix comprising "Cyr61"

which reads on world of polypeptide variants encompassing fragments, derivatives, analogs and homologs. The specification clearly teaches (page 48, lines 28+) that the polypeptides of the invention also extend to fragments, analogs, and derivatives of the full-length polypeptides. Additionally, the specification teaches (page 9, lines 17-25) that the polypeptides of the invention may be underivatized, or derivatized in conformity with a native or non-native derivatization pattern. Further, the polypeptides may encompass variants or polypeptides having different amino acid sequences. Thus, essentially, the claims are drawn to a **genus** of polypeptides that are only identified by a laboratory designation.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a structure in the form of a laboratory designation. Further, there is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a method for screening a modulator of cell migration comprising forming a gel matrix comprising SEQ ID NO:2 (murine Cyr61) or SEQ ID NO:4 (human Cyr61), but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
August 10, 2003